UNITED STATES PATENT AND TRADEMARK OFFICE

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10/510,500	03/07/2005	John P. Wikswo	14506-44191	9498

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EXAMINER
RIGGS II, LARRY D

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	**Applicant(s)**
Office Action Summary	10/510,500	WIKSWO ET AL.
	Examiner	**Art Unit**	
	LARRY D. RIGGS II	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>28 January 2009</u>.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6,8-10,13,14,28,31,33-37,48,51,53-56 and 66-73* is/are pending in the application.
    4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1,4,6,8-10,13,14,28,31,33-37,48,51,53-56 and 66-73* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    a)☐ All b)☐ Some * c)☐ None of:
    1.☐ Certified copies of the priority documents have been received.
    2.☐ Certified copies of the priority documents have been received in Application No. _____.
    3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.
4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application
6)☐ Other: _____.

DETAILED ACTION

Applicant's amendments filed 28 January 2009 and 19 June 2008 are

acknowledged and have been entered.

Status of Claims

Claims 2, 3, 5, 7, 11, 12, 29, 30, 32, 38-47, 49, 50, 52 and 57-65 are cancelled.

Claims 1, 4, 6, 8-10, 13, 14, 28, 31, 33-37, 48, 51, 53-56 and 66-73 are under pending

and examined on the merits.

Oath/Declaration

The newly executed Declaration filed on 28 January 2009 acknowledged and

accepted.

Withdrawn Rejections/Objections

The objection of the disclosure in the Office action mailed 20 October 2008 is

withdrawn in view of the arguments filed 28 January 2009. The amendments to the

specification filed 19 June 2008 have been entered.

The rejection of claims 1, 4, 6, 8-10, 13, 14, 28, 31, 33-37, 48, 51 and 53-56

under 35 U.S.C. 112, Second paragraph, in the Office action mailed 20 October 2008 is

withdrawn in view of the amendments and arguments filed 28 January 2009.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 4, 6, 8-10, 13, 14, 28, 31, 33-37, 48, 51, 53-56 and 66-73 are rejected

under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject

matter. In view of the reliance on recent CAFC decisions, the following grounds of

rejection is considered newly applied.

The recent en banc decision regarding Bilski v. Warsaw (2008) set forth that a

process is patent-eligible if (1) it is ties to a particular machine or apparatus or (2) it

transforms a particular article into a different state or thing. Further, the recent decision

in Comiskey (2009) confirmed the opinion set forth in Bilski of the prohibition pre-

empting an abstract idea or mental process in a claim. The revised Comiskey decision

further reiterated the president set forth in Richman, 563 F.2d 1026, 1030 (CCPA 1977)

wherein the court held the application unpatentable because "if a claim [as a whole] is

directed essentially to a method of calculating, using a mathematical formula, even if the

solution is for a specific purpose, the claimed method is nonstatutory."

The claims are drawn to a method of a method for discriminating an agent. The

instant claims are drawn to the abstract process steps of: (a) constructing a decision

tree having a plurality of branches, each branch corresponding to at least one defined

action, wherein each branch comprises a plurality of successive branches, each

successive branch corresponding to the at least one defined action; (b) providing a

conditioned environment sensitive to the agent; (c) obtaining data from response of the

agent to the conditioned environment; (d) extracting features from the obtained data; (e)

selecting a branch from the decision tree corresponding to the features; (f) performing

on the features the at least one defined action corresponding to the branch; (g)

producing a classification of the agent; (h) iteratively repeating steps of (d)-(g) until the

agent is discriminated with a desired corresponding confidence level, and (i) storing the

classification of the agent for use, wherein the method steps are performed by a

controller.

For these reasons, claims 1, 4, 6, 8-10, 13, 14, 28, 31, 33-37, 48, 51, 53-56 and

66-73 are considered directed to non-statutory subject matter.

Response to Arguments

Applicant's arguments filed 28 January 2009 have been fully considered but are

considered moot in light of the new grounds of rejection set forth above.

Claim Rejections - 35 USC § 103

This rejection is maintained and reiterated from the previous office action, mailed

19 March 2008.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1.   Determining the scope and contents of the prior art.
2.   Ascertaining the differences between the prior art and the claims at issue.
3.   Resolving the level of ordinary skill in the pertinent art.
4.   Considering objective evidence present in the application indicating
     obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of

the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g)

prior art under 35 U.S.C. 103(a).

Claims 1, 4, 6, 8-10, 13, 14 and 66-69 are rejected under 35 U.S.C. 103(a) as

being unpatentable over Wax (CH2847 IEEE, 1990, 2157-2160) in view of Li et al. (US

6,406,840) and further in view of Whitney (US Pat. Pub. 2002/0159642).

The claims are drawn to a method of A method for discriminating an agent,

comprising the steps of: (a) constructing a decision tree having a plurality of branches,

each branch corresponding to at least one defined action, wherein each branch

comprises a plurality of successive branches, each successive branch corresponding to

the at least one defined action; (b) providing a conditioned environment sensitive to the

agent; (c) obtaining data from response of the agent to the conditioned environment; (d)

extracting features from the obtained data; (e) selecting a branch from the decision tree

corresponding to the features; (f) performing on the features the at least one defined

action corresponding to the branch; (g) producing a classification of the agent; (h)

iteratively repeating steps of (d)-(g) until the agent is discriminated, and (i) storing the

classification of the agent for use.

Regarding claim 1, Wax shows a method of constructing a decision tree of

structured classifiers, wherein classification is carried out by a sequence of test

determined by the path in the tree that the object (agent) to be classified transverses

and the path taken from each node depends on the test result obtained at that node (i.e.

leaf), then when a terminal leaf is reached the object is assigned the class-tag

associated with that leaf, (see page 2157, right column, paragraphs 4 and 5; Figure 1).

Wax does not show steps b)-d), f) and h), providing a conditioned environment

sensitive to the agent, obtaining data from response of the agent to the conditioned

environment, extracting features from the obtained data, performing on the features at

least one defined action corresponding to the branch and repeating steps d)-g) until the

agent is discriminated.

Li et al. shows cell arrays for conducting comparative cell-based analyses,

wherein a biological or chemical agent are tested against numerous cell types, (see

column 12, line 45 - column 13, line 8; column 16, lines 7-30; Figure 1).

Wax and Li et al. do not show steps d), f) and h), extracting features from the

obtained data; performing on the features at least one defined action corresponding to

the branch, and iteratively repeating steps of (d)-(g) until the agent is discriminated.

Whitney shows a method for designing algorithms that allow fast retrieval,

classification, analysis and processing of data, (see paragraphs [0007-9]; Figure 1 and

5). Whitney shows automated pattern recognition process that may be applied across

diverse data types and used in virtually any field, (paragraph [0051]) wherein feature

selection performed from any data object or data set, (paragraph [0053-54],

[0081[0145]; Figures 7, 8, 14 and 20A-20E). Whitney shows the selection and training

of a classifier in order to assign a feature vector extracted form a data object to a

particular class, (see [0158]), wherein different classifiers can be used or refined with

respect to the feature to classify a data object to a respective class, (see paragraphs

[0068-0076]). Whitney shows a repeated feedback path that allows continually

modifying the process and if new feature selection is required, to correctly classify the

data object until a stopping condition is met, (see paragraphs [0077-78], [0083-0085];

Figures 1-5).

Regarding claim 4, Li et al. shows testing of a biological agent, (see column 12,

lines 26-44).

Regarding claim 6, Wax shows a best split rule of nodes according to the

minimum description length principle, (see 2159, left column, paragraphs 1-4).

Regarding claims 8-10, Li et al. shows providing data pertaining to possible viral

pathogens associated particular diseases and selecting cell types and exposing

selected cell types to a conditioned environment, (see column 12, line 9 - column 13, line 8; column 16, lines 7-30; Figure 1).

Regarding claims 13 and 14, Whitney shows selecting a feature extraction algorithm and classification method (classifier) from a library of algorithms, (see paragraph [0140]), and a plurality of classifications methods, wherein the classifier is applied to the extracted data feature to produce a classification, (see paragraph [0162-0163]).

Regarding claims 66-69, Whitney shows statistical confidence parameters of a classification that may be determined by a user, (paragraphs 73-74). It would be obvious for a user to choose to have 90% confidence levels for classification. Whitney shows a pattern recognition construction process that may be embodied as a system, a computer based platform, or provided as software code for execution on a general-purpose computer and storage on various computer readable fixed storage medium, (paragraphs 90, 211; Claim 22).

It would be obvious to one skilled in the arts to modify the method of tree structured classifiers by Wax with the method cellular assays with agent by Li et al. and the methods of feature selection and classification by Whitney because the agent specific data, feature selection of said data and subsequent classification of said features would be easily implemented in the splitting and pruning rules derived by Wax to better classify an agent of interest, (see Wax, page 2160, last two paragraphs). Therefore, one of ordinary skill in the art would recognize the claimed process as a

combination of routine applications that are well known the art that and produce no more than expected results.

Response to Arguments

Applicant's arguments filed 28 January 2009 have been fully considered but they are not persuasive.

Applicants argue that Wax, Li and Whitney taken alone or in combination, disclose, teach or suggest the invention, including the steps of 1) constructing a decision tree having a plurality of branches, each branch corresponding to at least one defined action, 2) performing on the features the at least one defined action corresponding to the branch, and 3) iteratively repeating steps of d-g until the agent is discriminated.   Applicants argue that the computational/experiment is an integrated process, where the data emerges form the process. Wax uses known, existing set of training data. The classifier by Wax is a result of tests run on the existing data set. Li and Whitney cannot cure the deficiencies of Wax. Applicants argue there is no motivation, no reasonable expectation of success and the combined art do not teach all the elements of the invention.

With regard to applicants argument directed to the deficiency of the teachings in the art, it is reiterated from the instant rejection that Wax shows a branched decision tree with each branch as a test and each node as a result of said test, (page 2157, right column, paragraphs 4 and 5; Figure 1). It would be obvious that a test may be an experiment or "defined action" such as provided by Li et al.

Wax shows using experimental data to construct a tree structured classifier to provide data results, (page 2159, right column – page 2160, left column). Li et al. shows cell arrays for conducting comparative cell-based analyses, wherein a biological or chemical agent are tested against numerous cell types and providing experimental data, (see column 12, line 45 - column 13, line 8; column 16, lines 7-30; Figure 1). It would be obvious that a test may include analyzing the effects of an agent on cell types.

Whitney shows a repeated feedback path that allows continually modifying the process and if new feature selection is required, to correctly classify the data object until a stopping condition is met, (see paragraphs [0077-78], [0083-0085]; Figures 1-5).

With regards to applicants argument that there is no motivation to combine the prior art teachings and, further, that there is no reasonable expectation of success from such a combination, it is noted that the Supreme Court rejected the application of a strict TSM test in the KSR v. Teleflex decision as being the only basis for establishing obviousness. In the instant rejection, it is maintained that all the elements of the claims are provided within the cited art. KSR International Co. v. Teleflex Inc., provides a rationale wherein a claim would have been obvious because a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. Motivation is not required to make a prima facie case of obviousness. It is enough to have a likelihood of success with known technical features in the prior art. It would be obvious to place method cellular assays with agent by Li et al. as the branches of the decision tree by Wax and combine the reiteration of steps to

result in a classification as provided in Whitney et al. because such a combination would

yield only familiar and expected results based on what is already known and established

in the prior art of record.

Claims 28, 31, 33-37, 48, 51, 53-56 and 70-73 are free of the art.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to LARRY D. RIGGS II whose telephone number is

(571)270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-

5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

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USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ERIC S. DEJONG/
Examiner, Art Unit 1631

/LDR/
Larry D. Riggs II
Examiner, Art Unit 1631